

## **Good Laboratory Practices**

### **CLIA Waived Tests**

#### Required

- ❑ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments – 1988) Certificate of Waiver (or higher level certificate)

Application [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)

- ❑ Perform any test categorized by FDA (Federal Drug Administration) as waived

List [www.accessdata.fda.gov/scripts/cdrh/cfdoc/cfCLIA/search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdoc/cfCLIA/search.cfm)

- ❑ Follow manufacturer's instructions for testing

See package insert or device manual

#### Personnel

- ❑ Director – no requirements
- ❑ Testing Personnel – no requirements

#### Oversight

- ❑ Cost - \$150 every two years
- ❑ Surveys

State agencies visit 2% of waived labs each year

Visit scheduled with facility

Surveyor uses educational approach